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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

CV 09-05700 PA (RCx)

MUTUAL PHARMACEUTICAL COMPANY, INC., a Pennsylvania corporation; AR SCIENTIFIC, INC., a Delaware corporation; and AR HOLDING COMPANY, INC., a Delaware corporation,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., a Nevada corporation; WEST-WARD PHARMACEUTICAL CORP,

Case No.

COMPLAINT FOR:

(1) FALSE AND MISLEADING ADVERTISING, FALSE REPRESENTATION OF FACT, AND UNFAIR COMPETITION UNDER 15 U.S.C. § 1125(A);
(2) UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE 17200, *ET SEQ.*;
(3) FALSE ADVERTISING

a Delaware corporation; GENERICS BIDCO I, LLC dba QUALITEST PHARMACEUTICALS, a Delaware corporation; VISION PHARMA, LLC, a New Jersey corporation; and EXCELLIUM PHARMACEUTICAL, INC., a New Jersey corporation,

Defendants.

UNDER CAL. BUS. & PROF. CODE § 17500, *ET SEQ.*; AND, (4) COMMON LAW UNFAIR COMPETITION AND MISAPPROPRIATION

DEMAND FOR JURY TRIAL

Plaintiffs Mutual Pharmaceutical Company, Inc. ("Mutual"), AR Scientific, Inc. ("AR Scientific") and AR Holding Company, Inc. ("AR Holding") (collectively "Plaintiffs"), complain and allege against Defendants Watson Pharmaceuticals, Inc., West-ward Pharmaceutical Corp., Generics Bidco I, LLC dba Qualitest Pharmaceuticals, Vision Pharma, LLC, and Excellium Pharmaceutical, Inc. (collectively, "Defendants") as follows.

INTRODUCTION

1. Plaintiffs bring this lawsuit under 15 U.S.C. § 1125(a), California Business and Professions Code §§ 17200 and 17500, and under the common law of unfair competition and misappropriation of the State of California, against manufacturers and marketers of unapproved prescription drug products containing colchicine as the sole active ingredient who are unlawfully and unfairly advertising, marketing, promoting, distributing, and/or selling their unapproved colchicine products in competition with Plaintiffs' colchicine product (COLCRYS™), which has been recently approved by the U.S. Food and Drug Administration ("FDA") and will be launched in the marketplace imminently.

2. Due to the proven public health concerns for drug safety and efficacy, it is against the law to market, distribute and/or sell any colchicine drug product that is not FDA-approved (21 U.S.C. § 301 *et seq.*).

3. On February 9, 2007, Mutual submitted Investigational New Drug application ("IND") No. 72,586 for colchicine.

4. Pursuant to the Orphan Drug Act ("ODA") (21 U.S.C. § 360aa-ee),

Mutual filed a Request for Orphan Drug Designation (Request No. 07-2458) on September 10, 2007.

5. Mutual's Request for Orphan Drug Designation was granted by the FDA on September 25, 2007.

6. On June 20, 2008, Mutual submitted a New Drug Application ("NDA") (NDA No. 22-352) for 0.6 mg tablets containing colchicine as the sole active ingredient pursuant to section 505(b) of the U.S. Food, Drug & Cosmetic Act (the "Federal FDCA"), 21 U.S.C. § 301 *et seq.*, for the treatment of Familial Mediterranean Fever ("FMF").

7. On September 30, 2008, Mutual submitted an NDA (NDA No. 22-351) for 0.6 mg tablets containing colchicine as the sole active pharmaceutical ingredient ("API") pursuant to section 505(b) of the Federal FDCA for the treatment of gout flares.

8. On July 29, 2009, Mutual obtained FDA approval to market and sell its COLCRYS™ colchicine (0.6 mg) product for the treatment of FMF.

9. Under the ODA, the FDA granted Mutual a 7-year period to exclusively market COLCRYS™ for the treatment of FMF, ending July 29, 2016.

10. On July 30, 2009, Mutual obtained FDA approval to market and sell its COLCRYS™ colchicine (0.6 mg) product for the treatment of gout flares.

11. Plaintiffs expect that the FDA will grant Mutual a 3-year period to exclusively market COLCRYS™ for the treatment of gout flares, ending July 30, 2012.

12. Information regarding the FDA's approval of COLCRYS™ is publicly available via the FDA website, as well as through various media outlets such as *The New York Times*. The COLCRYS™ label is also available to the public through the FDA website.

13. While Mutual is the manufacturer of its FDA-approved COLCRYS™ product, Plaintiffs AR Scientific and AR Holding share in ownership, distribution

or licensing rights in the product, as set forth in more detail herein.

14. Presently, Plaintiffs are the only lawful providers of an FDA-approved drug product containing colchicine as the sole active ingredient.

15. Despite Plaintiffs' unique status as the only entities that can lawfully manufacture and market a drug product containing colchicine as the sole active ingredient in the United States, Defendants nevertheless manufacture and market their unapproved colchicine products throughout the United States, including the State of California.

16. Moreover, through a variety of means detailed herein, Defendants market, promote and sell their illegal colchicine products by relying on false and misleading statements, omissions and other tactics likely to (a) create false impressions and confusion regarding the safety, efficacy and FDA approval status of their colchicine products and, concomitantly, Plaintiffs' COLCRYS™ product, and (b) cause pharmacists, physicians, buyers and consumers to mistakenly conclude that Defendants' colchicine products are either interchangeable with Plaintiffs' FDA-approved COLCRYS™ product or, even worse, that Defendants' products are safer than Plaintiffs' FDA-approved COLCRYS™ product – whereas the opposite is true.

17. Defendants' unlawful marketing, advertising, promotion and distribution not only cause confusion, but irreparably harm Plaintiffs and pose grave risks to California consumers as well as to others.

18. Defendants' misleading and unlawful marketing and distribution practices include the distribution of false and misleading labels, product inserts, product advertising and drug information through a variety of channels, including: (a) integrated drug dispensing databases and pricing services commonly known as "Price Lists" (hereinafter referred to as "Price Lists") such as Medi-Span, First Databank, Gold Standard and Redbook; (b) drug product ordering systems provided by drug wholesalers (hereinafter referred to as "Wholesaler Ordering Systems"),

such as McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda, Inc. and Kinray, Inc.; (c) drug ordering systems used by retail drugstore chains; and (d) numerous third-party Internet drug product retailers and wholesalers.

19. Defendants' use of misleading, obsolete and/or incomplete information on packaging, labeling and "instructions for use" for their illegal colchicine products creates confusion among pharmacists, physicians, buyers and consumers, and enhances the harm to Plaintiffs and health risks to patients.

20. Plaintiffs bring this action to enjoin Defendants' ongoing violations of the Lanham Act and Sections 17200 and 17500 of the California Business and Professions Code, and common law unfair competition including false advertising and misappropriation, and seek to prohibit Defendants from falsely advertising, marketing, promoting and/or distributing their unapproved colchicine products. Plaintiffs ask the Court to immediately enjoin the Defendants' unsafe, unfair, and unlawful advertising, marketing and sales activities. Plaintiffs also seek damages resulting from Defendants' unfair and unlawful conduct as set forth in the Prayer for Relief herein.

PARTIES

PLAINTIFF MUTUAL PHARMACEUTICAL COMPANY, INC.

21. Plaintiff Mutual Pharmaceutical Company, Inc. ("Mutual") is a corporation organized under the laws of the State of Pennsylvania and has its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

22. Mutual is a pharmaceutical company that focuses on drug development, marketing, and distribution, and offers a wide range of products, including its COLCRYS™ product, which will be marketed and distributed imminently.

PLAINTIFF AR SCIENTIFIC, INC.

23. Plaintiff AR Scientific, Inc. ("AR Scientific") is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

24. AR Scientific is a pharmaceutical company that focuses on the marketing and distribution of branded pharmaceutical products, including its COLCRYS™ product, which will be marketed and distributed imminently.

25. AR Scientific has the right to distribute any approved products covered by the scope of NDA No. 22-351 and NDA No. 22-352.

PLAINTIFF AR HOLDING COMPANY, INC.

26. Plaintiff AR Holding Company, Inc. ("AR Holding") is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1105 N. Market Street, Suite 1300, Wilmington, Delaware 19801.

27. AR Holding Company is a pharmaceutical company that focuses on the management and protection of intellectual property rights related to branded pharmaceutical products, including its COLCRYS™ product, which will be marketed and distributed imminently.

28. Mutual has assigned to AR Holding all right, title and interest in NDA No. 22-351 and NDA No. 22-352 for colchicine tablets and all know-how, material permits, consents and approvals, retaining a license to make, use, offer for sale, sell, import, develop and commercialize the products covered by the scope of NDA No. 22-351 and NDA No. 22-352 and retaining its status as regulatory agent responsible for all FDA regulatory filings.

29. All Plaintiffs retain rights in commercializing any products covered by the scope of NDA No. 22-351 and NDA No. 22-352 and are irreparably harmed by the unfair competition and deception complained of herein.

DEFENDANT WATSON PHARMACEUTICALS, INC.

30. On information and belief, Defendant Watson Pharmaceuticals, Inc.

("Watson") is a corporation organized under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

31. On information and belief, Watson's principal business is marketing and selling allegedly "generic" versions of popular brand name prescription drug products.

32. On information and belief, Watson imports, causes others to import, or purchases from others that import, colchicine API, which it uses to produce colchicine products.

33. On information and belief, Watson advertises, promotes, markets and sells drug products having colchicine as the sole active ingredient, and in particular 0.6 mg colchicine tablets having colchicine as the sole active ingredient, throughout the United States, in California, and in this judicial district.

34. On information and belief, Watson has not obtained, nor ever sought to obtain, FDA approval for products containing colchicine as the sole active ingredient.

DEFENDANT WEST-WARD PHARMACEUTICAL CORP.

35. On information and belief, Defendant West-ward Pharmaceutical Corp. ("West-ward") is a corporation organized under the laws of the State of Delaware, having a principal place of business at 465 Industrial Way West, Eatontown, New Jersey 07724.

36. On information and belief, West-ward's principal business is marketing and selling allegedly "generic" versions of popular brand name prescription drug products.

37. On information and belief, West-ward imports, causes others to import, or purchases from others that import, colchicine API, which it uses to produce colchicine products.

38. On information and belief, West-ward advertises, promotes, markets

and sells drug products having colchicine as the sole active ingredient, and in particular 0.6 mg colchicine tablets having colchicine as the sole active ingredient, throughout the United States, in California, and in this judicial district.

39. On information and belief, West-ward has not obtained, nor ever sought to obtain, FDA approval for products containing colchicine as the sole active ingredient.

DEFENDANT GENERICS BIDCO I, LLC DBA QUALITEST PHARMACEUTICALS

40. On information and belief, Defendant Generics Bidco I, LLC dba Qualitest Pharmaceuticals ("Qualitest") is a corporation organized under the laws of the State of Delaware, having a principal place of business at 130 Vintage Drive, Huntsville, Alabama 35811.

41. On information and belief, Qualitest's principal business is marketing and selling allegedly "generic" versions of popular brand name prescription drug products.

42. On information and belief, Qualitest imports, causes others to import, or purchases from others that import, colchicine API, which it uses to produce colchicine products.

43. On information and belief, Qualitest advertises, promotes, markets and sells drug products having colchicine as the sole active ingredient, and in particular 0.6 mg colchicine tablets having colchicine as the sole active ingredient, throughout the United States, in California, and in this judicial district.

44. On information and belief, Qualitest has not obtained, nor ever sought to obtain, FDA approval for products containing colchicine as the sole active ingredient.

DEFENDANT VISION PHARMA, LLC

45. On information and belief, Defendant Vision Pharma, LLC ("Vision") is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 1973 Highway 34, Suite E22, Wall, New Jersey 07719.

46. On information and belief, Vision's principal business is marketing and

selling allegedly "generic" versions of popular brand name prescription drug products.

47. On information and belief, Vision imports, causes others to import, or purchases from others that import, colchicine API, which it uses to produce colchicine products.

48. On information and belief, Vision advertises, promotes, markets and sells drug products having colchicine as the sole active ingredient, and in particular 0.6 mg colchicine tablets having colchicine as the sole active ingredient, throughout the United States, in California, and in this judicial district.

49. On information and belief, Vision has not obtained, nor ever sought to obtain, FDA approval for products containing colchicine as the sole active ingredient.

DEFENDANT EXCELLIUM PHARMACEUTICAL, INC.

50. On information and belief, Defendant Excellium Pharmaceutical, Inc. ("Excellium") is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 3-G Oak Rd, Fairfield, New Jersey 07004.

51. On information and belief, Excellium's principal business is marketing and selling allegedly "generic" versions of popular brand name prescription drug products.

52. On information and belief, Excellium imports, causes others to import, or purchases from others that import, colchicine API, which it uses to produce colchicine products.

53. On information and belief, Excellium advertises, promotes, markets and sells drug products having colchicine as the sole active ingredient, and in particular 0.6 mg colchicine tablets having colchicine as the sole active ingredient, throughout the United States, in California, and in this judicial district.

54. On information and belief, Excellium has not obtained, nor ever sought to obtain, FDA approval for products containing colchicine as the sole active ingredient.

JURISDICTION AND VENUE

55. This action arises under 15 U.S.C. § 1125(a), and under the statutory and common law of the State of California. This Court has subject matter jurisdiction for each of the claims herein as follows:

(a) False or misleading representation of fact and unfair competition in violation of the Lanham Act, § 43(a), 15 U.S.C. § 1125(a), with original jurisdiction vested in this Court by virtue of 15 U.S.C. § 1121 and 28 U.S.C. § 1338;

(b) Statutory unfair competition arising under California Business and Professions Code § 17200, *et seq.*, with supplemental jurisdiction vested in this Court by virtue of 28 U.S.C. § 1367(a);

(c) Statutory false advertising arising under California Business and Professions Code § 17500, *et seq.*, with supplemental jurisdiction vested in this Court by virtue of 28 U.S.C. § 1367(a); and

(d) Common law unfair competition and misappropriation arising under the laws of the State of California, with supplemental jurisdiction vested in this Court by virtue of 28 U.S.C. § 1367(a).

56. This Court also has jurisdiction over the claims pursuant to 28 U.S.C. § 1331.

57. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Defendants because they have extensive contacts with the State of California and this judicial district including by virtue of the fact that they have caused their colchicine products to be advertised, promoted, and sold in this judicial district; the causes of action asserted in this Complaint arise out of those contacts; and Defendants regularly do business in this district.

58. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c) because Defendants have extensive contacts with the State of California and this judicial district including by virtue of the fact that they have caused their colchicine

products to be advertised, promoted and sold in this judicial district; the causes of action asserted in this Complaint arise out of those contacts; and Defendants regularly do business in this district.

FACTUAL BACKGROUND

FMF, GOUT AND COLCHICINE

59. Colchicine is an alkaloid derived from the plant of the Lily family *Colchicum autumnale*. Plant extracts containing colchicine have been used to treat gout for more than two thousand years, and pseudogout and Familial Mediterranean Fever ("FMF") for several decades. The active pharmacological component of the plant, colchicum, was isolated in 1820 and, in 1883, a fairly pure colchicum was extracted and subsequently called colchicine. Colchicine is a drug with both a narrow therapeutic-toxicity window and a marked variability between individuals in drug disposition. *See* Terkeltaub R., "Colchicine Update: 2008," Semin. Arthritis Rheum (in press).

60. While colchicine, when taken properly, has proven to be effective in the treatment of FMF and gout, drugs containing colchicine can have serious health and safety risks if not administered properly.

61. According to information culled from the FDA's Spontaneous Reporting System (Adverse Drug Reaction (ADR) Database, covering data from January 1, 1969 through October 31, 1997) and the Adverse Event Reporting System (AERS Database, covering data from November 1, 1997 through June 30, 2007), as of January 15, 2008 there were 751 reports in which colchicine was a suspect or interacting drug and there were 234 reports with death listed as the outcome. Significantly, the majority of the death reports were associated with oral colchicine (169 of 234; ~72%), which is consistent with the vastly greater use of the oral product. Less than 10% of death reports (21 of 234) were associated with intravenous use of colchicine.

62. Similarly, the World Health Organization ("WHO") summary of safety for colchicine showed 1,380 adverse reports submitted from 79 countries between

1968 and March 2006. Overall, among these reports, gastrointestinal adverse events, diarrhea, vomiting and nausea were the most common. Noteworthy serious events include acute renal failure, thrombocytopenia, leucopenia and death.

63. FMF is an inherited disorder characterized by recurrent bouts of fever and peritonitis, sometimes with pleuritis, skin lesions, arthritis and, rarely, pericarditis. FMF may lead to the development of renal amyloidosis, which in turn may result in renal failure. FMF occurs frequently in people having genetic origins in the Mediterranean basin, though it has occurred in other populations such that it should not be diagnosed solely on the basis of ancestry. The onset of the condition usually occurs between age 5 and 15 years, but can occur later or much earlier. *See* THE MERCK MANUAL, 18TH ED., Merck Research Laboratories (2006). If untreated, FMF can be fatal.

64. FMF "affects less than 200,000 persons in the United States," qualifying it as a "rare disease or condition." The FDA and Congress refer to drugs that treat such rare diseases as "orphan drugs." *See* 21 U.S.C. § 360bb(a)(2).

65. To encourage the development and ensure the supply of FDA-approved drugs that combat rare diseases, Congress passed the ODA. The key provision of the ODA is the 7-year period of Orphan Drug Exclusivity ("ODE") awarded to the first company that successfully invests in and obtains final FDA approval for an orphan-designated drug.

66. Gout results from the precipitation of monosodium urate crystals into tissue most usually in joints causing recurring acute arthritis or chronic arthritis. *See* THE MERCK MANUAL, 18TH ED., Merck Research Laboratories (2006).

67. Gout is one of the most common forms of inflammatory arthritis. It frequently results in significant short-term disability, occupational limitations, and utilization of medical services.

68. According to a 2002 National Ambulatory Medical Care survey, there were 3.9 million visits for (acute or chronic) gout of the 973 million ambulatory

care visits in the United States. *See* Krishnan E, Lienesch D, Kwoh CK, "Gout in Ambulatory Care Settings in the United States," J. Rheumatol. 35, 498-501 (2008).

69. Acute gout (i.e gout flares) is characterized, at least initially, by intense pain and swelling at the site of urate accumulation, often initially within the metatarsophalangeal joint of the big toe. The urate crystals can accumulate in and around joints to form firm yellow or white papules/nodules called tophi. *See* THE MERCK MANUAL, 18TH ED., Merck Research Laboratories (2006).

70. It is estimated that 3 to 5 million individuals in the United States experience acute gout attacks and/or suffer from chronic gout. *See* Krishnan E, Lienesch D, Kwoh CK, "Gout in Ambulatory Care Settings in the United States," J. Rheumatol. 35, 498-501 (2008).

71. Colchicine has been used to treat acute gout, and has also been used as a prophylactic treatment. *See* THE MERCK MANUAL, 18TH ED., Merck Research Laboratories (2006).

FDA WARNINGS CONCERNING COLCHICINE AND OTHER UNAPPROVED DRUGS

72. Since at least as early as June 2006, the FDA has emphasized that unapproved drugs represent a public health threat:

> The Food and Drug Administration ("FDA") announced the strengthening of its efforts against unapproved drug products.
>
> * * *
>
> "Right now, many unapproved drugs represent a public health threat because consumers wrongly assume that these widely marketed and available drugs are approved and have been found to be safe and effective by the FDA," said Acting FDA Commissioner Dr. Andrew von Eschenbach. "While we want to ensure continued patient access to necessary treatments, as a physician I feel strongly that patients expect and deserve all their prescription medicines to be FDA approved. These unapproved drugs have bypassed the agency approval process through which FDA ensures, based on reliable scientific data, that marketed drugs are safe, effective, properly manufactured, and accurately labeled. (Emphasis added)

"FDA Acts to Improve Drug Safety and Quality," FDA website at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108665.

htm (June 8, 2006) (emphasis added).

73. The FDA has recognized there is an additional problem of confusion among healthcare providers about non-FDA approved drugs:

> There are several reasons why an unapproved drug may be available. *One example is when only one company may have approval to market a drug, but other companies are illegally marketing their versions of the drug without having gone through the FDA's approval process. Another scenario is that a combination of ingredients is approved by the FDA, but a company is marketing a single ingredient without approval.*
>
> Some older products continue to be marketed illegally for historical reasons. "Many drugs were marketed before Congress made changes to the law requiring drugs to undergo FDA review," [Deborah] Autor [, Director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research,] says. There are unapproved drugs whose makers claim the drugs are "grandfathered" under older standards and therefore don't require approval under the current regulatory framework. "But the truly 'grandfathered' drugs represent only a few, at most, of all the unapproved drugs being marketed," Autor says. *"Most unapproved drugs do require FDA approval."*
>
> * * *
>
> Some drugs have been sold for so many years that physicians and pharmacists may not know they are unapproved. They even may be unaware that unapproved drugs are advertised in medical journals and listed in the Physicians' Desk Reference (PDR) and other reference books. *These practices give the false impression that the drugs were reviewed and approved by the FDA.*

M. Meadows, "The FDA takes action against unapproved drugs." FDA Consumer Magazine. January-February 2007. (emphasis added).

74. Significantly, on February 6, 2008, prior to the approval of Mutual's NDAs, the FDA issued a statement that it "strongly encourages the manufacturers of [unapproved drugs] to pursue FDA approval." In particular, the FDA stated with regard to unapproved colchicine drug products:

> There are no approved products that contain only colchicine as an active ingredient.
>
> ***
>
> Like all other unapproved drugs, colchicine tablets that are marketed without FDA approval could be subject to FDA enforcement at any time. Accordingly, FDA strongly encourages the manufacturers of those products to pursue FDA approval.

"Questions and Answers About FDA's Enforcement Action Against Unapproved Injectable Colchicine Products," FDA website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm119642.htm (February 6, 2008).

75. The FDA further warned that:

> Colchicine is a highly toxic drug that can easily be administered in excessive doses, especially when given intravenously. There is a narrow margin between an effective dose of the drug and a toxic dose that can result in serious health risks, including death.

See "FDA Takes Action to Stop the Marketing of Unapproved Injectable Drugs Containing Colchicine," FDA website at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116853.htm (February 6, 2008).

76. Additional news articles or stories indicate that the marketing of such non-FDA approved drugs and uncertified medicines is "a serious safety issue" and further illustrate consumer confusion. *See* Robert Cohen, "Uncertified Medicines a 'Serious' Safety Issue, Thousands of Drugs lack FDA Approval," THE STAR LEDGER, (July 9, 2006) and Helen Palmer, "Unapproved Drugs, by Prescription," MARKETPLACE, http://marketplace.publicradio.org/display/web/2006/06/09/unapproved_drugs_by_prescription/ (June 9, 2006); Rita Rubin, "Hundreds of Unapproved Drugs Sold by Prescription," USATODAY, http://www.usatoday.com/news/health/2006-09-17-unapproved-drugs-cover_x.htm (September 18, 2006); Marc Kaufman , "Unapproved Drugs Called 'Threat'," THE WASHINGTON POST, http://www.washingtonpost.com/wp-dyn/content/article/2006/06/08/AR2006060801542.html (June 9, 2006).

ONLY PLAINTIFFS HAVE FDA APPROVAL TO MARKET A PRODUCT HAVING COLCHICINE AS THE SOLE ACTIVE INGREDIENT

77. In part due to the publication of the revised Compliance Policy Guide

("CPG") on marketed unapproved drugs in June 2006 and the simultaneous publication of the related guideline (and subsequently the February 2008 guideline) and news releases referenced in this Complaint, the industry has long had notice that NDAs were required and would have to be submitted by anyone who wanted to legally market drug products containing colchicine as the sole active ingredient.

78. Thus, the industry has been aware that it would be necessary to establish the efficacy and safety of drug products containing colchicine as the sole active ingredient (through the filing of NDAs supported by clinical data) in order to obtain FDA approval and to legally market such colchicine drugs.

79. Unlike any other entity to date, Mutual undertook the steps and expenses necessary to establish the safety and efficacy of drug products containing colchicine as the sole active ingredient for purposes of obtaining FDA approval.

80. As noted above, Mutual followed FDA procedures and submitted an IND for colchicine on February 9, 2007, followed by a Request for Orphan Drug Designation on September 10, 2007 (which was granted by the FDA on September 25, 2007).

81. Mutual subsequently submitted a series of NDAs related to the safe and effective use of its COLCRYS™ product for various conditions:

Indication	NDA Submission Date	Approval Date
FMF	June 20, 2008	July 29, 2009
Gout Flares	September 30, 2008	July 30, 2009

82. On July 29, 2009, after a review of clinical studies demonstrating the safety and effectiveness of Mutual's 0.6 mg tablets containing colchicine as the sole active ingredient in treating FMF, the FDA approved Mutual's NDA and granted Mutual a 7-year ODE to exclusively market and sell COLCRYS™ for the treatment of FMF until July 29, 2016.

83. On July 30, 2009, after a review of clinical studies demonstrating the safety and effectiveness of Mutual's 0.6 mg tablets containing colchicine as the sole

active ingredient in treating gout flares, the FDA approved Mutual's NDA and is expected to grant Mutual a 3-year period to exclusively market and sell COLCRYS™ for the treatment of gout flares until July 30, 2012.

84. As such, no other companies can obtain FDA approval for a drug product containing colchicine as the sole active ingredient for the treatment of either FMF or gout flares until after the expiration of the respective exclusivity periods.

85. The FDA's approval was based in part on its comprehensive review of clinical studies demonstrating the safety and efficacy of Mutual's COLCRYS™ product, and FDA inspections of Mutual's manufacturing facilities.

86. Mutual's FDA-approved COLCRYS™ product provides physicians and patients with a predictable, safe and effective treatment for the symptoms of both FMF and gout flares.

87. In order to obtain the data sufficient to submit its various NDAs to support FDA approval of COLCRYS™, Mutual has spent millions of dollars to develop its COLCRYS™ formulation and establish its safety and efficacy for treatment of both FMF and gout flares.

88. These costs have included those associated with conducting several clinical trials which comprise, among other things, performing pharmacokinetic and clinical studies and reporting clinical data to the FDA, as well as regulatory, legal and manufacturing costs.

89. Mutual designed and conducted a multicenter, randomized, double-blind, placebo-controlled, parallel group, dose comparison study in which 185 adults (out of a total of 575 trial participants) were exposed to at least one dose of COLCRYS™ to demonstrate the safety and efficacy of its product. Mutual's study was referred to as the Acute Gout Flare Receiving Colchicine Evaluation ("AGREE") Trial (Clinical Trial MPC–004-06-001).

90. In the AGREE trial, patient adverse events were monitored throughout.

Among other things, patients were instructed to record pain, dosing and gastrointestinal tolerability.

91. Thereafter, Mutual sponsored six additional pharmacokinetic studies in which 119 healthy volunteers were exposed to at least one dose of COLCRYS. In all six studies, adverse events were monitored throughout. Clinical laboratory tests, including hematology, blood chemistries and urinalysis, were obtained at screening, study check-in, and discharge.

92. Plaintiffs' efforts resulted in the discovery and development of new dosing regimens with COLCRYS that reduce the total amount of colchicine used by patients and which in turn result in a significant decrease in the most common side effects from colchicine use (*i.e.*, adverse effects involving the gastrointestinal tract, including cramping, nausea, diarrhea, abdominal pain and vomiting). In fact, the clinical trials established that patients have historically been given approximately three times the necessary colchicine dosage to achieve the desired effect despite a narrow therapeutic index.

93. Additionally, as illustrated in the below table, through these efforts Plaintiffs have discovered potentially serious drug interactions between colchicine and certain other drugs, as well as specific dosing regimens that help ameliorate potential negative interactions.

Drug	**Noted or Anticipated Outcome**	**Clinical Comment**	
Strong CYP3A4 Inhibitors			
atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin	Significant increase in colchicine plasma levels; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors.	**Gout Flares** 0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (half tablet) 1 hour later. Dose to be repeated no earlier than 3 days.	**FMF** Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors			
amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, verapamil	Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.	**Gout Flares** 1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.	**FMF** Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)
P-gp Inhibitors			
cyclosporine, ranolazine	Significant increase in colchicine plasma levels; fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other P-gp inhibitors.	**Gout Flares** 0.6 mg (1 tablet) x 1 dose. Dose to be repeated no earlier than 3 days.	**FMF** Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

(Note: Chart reproduced from the FDA-approved product label/insert for COLCRYS™ for the treatment of FMF and gout flares).

94. Defendants' product labels/inserts do not include any information on specific dosing regimens that help ameliorate potential negative drug interactions.

95. Moreover, Mutual is actively investing resources to create and maintain a stockpile of COLCRYS™ in order to meet anticipated demand for the product, which will require additional expenditures. Mutual currently has enough finished product to supply four months of COLCRYS™ at the current market demand. Mutual also has enough API to manufacture another 140,000,000 COLCRYS™ tablets to meet future market demand.

96. To date, no other company has invested the time, energy and money to obtain Orphan Designation or seek FDA approval for another drug product containing colchicine as the sole active ingredient.

DEFENDANTS FALSELY ADVERTISE AND MARKET THEIR UNAPPROVED COLCHICINE DRUG PRODUCTS AS BEING SAFE, EFFECTIVE, AND FDA-APPROVED, THROUGH THE USE OF PRICE LISTS AND WHOLESALER ORDERING SYSTEMS

97. The Federal FDCA explicitly *prohibits* the commercial distribution and marketing of prescription drugs that lack an approved NDA. 21 U.S.C. § 351(d), 355(a).

98. Nevertheless, upon information and belief, Defendants advertise, market, sell and distribute their unapproved and illegal colchicine drug products to a wide array of purchasers through a variety of commercial channels of trade throughout the United States.

99. The purchasers of Defendants' unapproved colchicine products include, but are not limited to, various national and regional drugstore chains, wholesale generic buyers and independent pharmacies.

100. In addition to the foregoing direct purchasers, three other categories of individuals play important roles in purchases of Defendants' products: physicians, who prescribe colchicine drug products; pharmacists, who fill prescriptions for such products; and patients, who ultimately use Defendants' unapproved and dangerous colchicine products.

101. To advertise, market, sell, and distribute their unapproved and illegal colchicine products, Defendants disseminate advertisements and product information through several advertising channels, including Price Lists, Wholesaler Ordering Systems, pharmacy computers and websites.

102. Price Lists provide drug and pricing databases which may be integrated with other computerized information systems used by, among others, pharmacists, insurance companies and buyers to obtain information material to decisions regarding the prescription, dispensing, and purchasing of drug products, and also to automatically provide drug information that patients need for safe use of their drugs. The Price Lists include, but are not limited to, Medi-Span, First Databank, Gold Standard and Redbook.

103. Among other resources, pharmacists rely on the drug databases provided by the Price Lists to determine whether a drug prescribed to a patient may cause fatal or other injurious interactions with other drugs being taken by the patient; to avoid dispensing the wrong drug or the wrong dosage of a drug; to obtain instructions for use; and to make sure drugs are dispensed with appropriate cautionary labels and other patient information.

104. As an example of the information provided by the Price Lists, Medi-Span indicates on its website that it "provides pharmacists with the up-to-date, accurate and comprehensive drug information they need to support drug dispensing activities in inpatient, outpatient, specialty and mail-order pharmacies." (*See* http://www.medispan.com/pharmacies.aspx.)

105. The information provided by the Price Lists also assists governmental and private health plans with improving the quality of care and reducing medication costs for their beneficiaries by minimizing the prescribing and dispensing of drugs that are medically inappropriate and/or less cost-effective than alternative drugs.

106. Wholesaler Ordering Systems allow pharmacists to select and purchase drug products that they intend to dispense in their pharmacies. Many wholesalers—including, but not limited to, McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda, Inc. and Kinray, Inc.—provide their Wholesaler Ordering Systems to pharmacists over the Internet.

107. After a pharmacist selects and purchases a drug product listed on a Wholesaler Ordering System, the wholesaler delivers the drug product directly to the pharmacy or any other location specified by the pharmacist or his/her headquarters.

108. Drug manufacturers, such as the Defendants, must take affirmative steps to provide the drug and pricing information for their unapproved colchicine products to various advertising channels, including the Price Lists and Wholesaler Ordering Systems.

109. On information and belief, Defendants supply misleading, obsolete

and/or incomplete information about their unapproved and illegal colchicine products to the Price Lists, Wholesaler Ordering Systems, and other advertising channels.

110. For example, on information and belief, First Databank, one of the largest Price Lists, requires that drug manufacturers submit an FDA letter of approval when submitting a new prescription drug for listing on First Databank. Thus, on information and belief, in order to be listed on First Databank, Defendants Excellium, Vision, Watson, and West-ward either misrepresented to First Databank that their unapproved colchicine products were FDA-approved or that their unapproved colchicine products did not need to be approved by the FDA in order to be sold lawfully.

111. In addition, on information and belief, Defendants Watson, Excellium and West-ward have provided misleading, obsolete, and/or incomplete information about the FDA-approval status of their unapproved colchicine products to Anda, Inc. (which in fact is owned by Defendant Watson), one of the largest distributors of generic pharmaceuticals in the U.S., which resulted in the display on Anda's Wholesaler Ordering System of a false "AB" rating for Watson's unapproved colchicine product and a misleading "NR" rating for Excellium's and West-ward's unapproved colchicine products. The "AB" rating for Watson's unapproved colchicine product is likely to mislead consumers into believing that the product has been approved by the FDA because only drugs that are approved by the FDA and determined to be therapeutically equivalent to an FDA-approved drug can be designated with an "AB" rating. Further, relevant consumers are likely to mistakenly believe that the "NR" rating for Excellium's and West-ward's unapproved colchicine products means that their products do not need to be approved by the FDA in order to be sold lawfully.

112. Likewise, on information and belief, Defendants Excellium, Watson, Vision, and West-ward provided misleading, obsolete, and/or incomplete

information about the FDA-approval status of their unapproved colchicine products to Kinray, Inc., one of the largest privately-held drug wholesalers, which resulted in the display of a misleading "NR" or "N/A" rating on Kinray's Wholesaler Ordering System. Again, relevant consumers are likely to mistakenly believe that the "NR" or "N/A" rating means that their unapproved colchicine products do not need to be approved by the FDA in order to be sold lawfully.

113. On information and belief, Defendants are aware that pharmacists and buyers believe that all prescribed drugs identified on the Price Lists and the Wholesaler Ordering Systems are safe, effective and FDA-approved.

114. Survey evidence demonstrates the inaccurate perception of relevant consumers that pharmacy computer systems, which incorporate information from Price Lists and Wholesaler Ordering Systems, perform a gatekeeper function by displaying only those drug products that have been approved by the FDA.

115. Thus, by listing their unapproved and illegal colchicine products on the Price Lists, Wholesaler Ordering Systems, and other advertising channels, Defendants knowingly and willfully communicate to relevant consumers that their products are safe, effective and FDA-approved. These statements are misleading and material to drug purchasing decisions.

116. Defendants' sale of their unapproved and illegal colchicine products through the Price Lists and Wholesaler Ordering Systems is particularly detrimental to Plaintiffs because the Price Lists and Wholesaler Ordering Systems are the primary channels of trade used to advertise, market and sell drug products.

DEFENDANTS ALSO MARKET AND SELL THROUGH INTERNET PHARMACIES, WHICH THEY KNOW OR SHOULD KNOW ARE FALSELY ADVERTISING DEFENDANTS' UNAPPROVED COLCHICINE PRODUCTS AS BEING SAFE, EFFECTIVE AND FDA-APPROVED

117. On information and belief, Defendants have intentionally caused their unapproved colchicine products to be advertised and sold nationally, including in California, on the websites of various Internet pharmacy retailers and wholesalers.

For example, Defendants advertise and/or make available their illegal colchicine products on buygenericdrugs.com. (*See* http://www.buygenericdrugs.com/price_search.aspx?drugname=colchicine)

118. With regard to illegal sales of Defendants' colchicine products at buygenericdrugs.com, the website contains misleading and false statements that are likely to mislead consumers into believing that Defendants' colchicine products are FDA-approved. For example, the buygenericdrugs.com site includes the following statements: (1) "FDA Approved Generic Prescription Drugs" and (2) "Save on FDA Approved Generic Drugs Today." (*See* http://www.buygenericdrugs.com/)

119. Similarly, the buygenericdrugs.com website contains a stylized FDA symbol, and states that "All generic drugs have been approved for use by the Food and Drug Administration"—including Defendants' unapproved colchicine products, which are offered for sale on the website. (*See* http://www.buygenericdrugs.com/)

120. Additionally, at the bottom of the web page from which consumers can order illegal colchicine product from buygenericdrugs.com, consumers are presented with the following misleading claim: "We are an American based company offering FDA approved generics." (*See* http://www.buygenericdrugs.com/price_search.aspx?drugname=colchicine)

121. Defendants know, or should know, that buygenericdrugs.com makes false representations relating to their colchicine products. However, upon information and belief, Defendants continue to market and sell their unapproved colchicine products through buygenericdrugs.com despite the website's false statements, thereby becoming complicit in, and contributorily liable for, buygenericdrugs.com's wrongful acts.

122. On information and belief, Defendants knew, or reasonably should have known, that Internet retailers (such as buygenericdrugs.com) that sell Defendants' colchicine products market them as FDA-approved generic drugs to an unsuspecting public.

123. On information and belief, Defendants have taken affirmative steps to display false and/or misleading information on the Internet websites that misrepresent that Defendants' colchicine products are safe, effective and FDA-approved.

DEFENDANTS' LABELING AND INSTRUCTION MATERIALS FOR UNAPPROVED COLCHICINE PRODUCTS ARE DANGEROUS AND LIKELY TO DECEIVE PURCHASERS/USERS

124. Due to Mutual's extensive work qualifying its COLCRYS™ product, process, and facilities for FDA approval, the labeling of Mutual's COLCRYS™ product lists and warns of numerous drug-drug interactions, food interactions and contraindications, including potentially fatal health risks due to the interaction of colchicine with clarithromycin and ritonavir, as well as new significant safety information regarding the dangerous accumulation of colchicine during chronic (*i.e.*, prophylactic) dosing.

125. Defendants' labels fail to mention many of the drug-drug interactions, food interactions and contraindications required by the FDA on Mutual's approved label. For example, the incomplete contraindication warnings on Defendants' product insert/labels fail to mention that patients with renal or hepatic impairment should not be given colchicine in conjunction with P-gp or strong CYP3A4 inhibitors since these patients face life-threatening and fatal colchicine toxicity even when taken in therapeutic doses.

126. The FDA has also required Mutual to include a Medication Guide with its COLCRYS™ product, which includes important warnings regarding various drug-drug interactions (e.g. ketoconazole and nefazodone) and food interactions (e.g. grapefruit and grapefruit juice). The Medication Guide is written so that consumers can easily understand the serious health risks involved when taking COLCRYS™ in combination with certain foods and drugs.

127. On information and belief, Defendants do not include Medication Guides with their unapproved products.

128. As noted in this Complaint, colchicine is not an innocuous drug and is

a narrow therapeutic index drug with significant risk for adverse reactions from drug accumulation or drug-drug interactions. If incorrectly administered, colchicine can pose serious health risks—including the risk of death. The risks of colchicine are appropriately managed only through proper administrative approval and labeling according to FDA regulations.

129. Mutual has demonstrated that colchicine blood levels increase approximately 250% when coadministered with ritonavir or clarithromycin. Had Mutual not conducted the safety studies required for FDA approval, this potentially serious accumulation would not be documented.

130. Additionally, Mutual discovered that after 10 days of "traditional" dosing of two tablets a day—as recommended by Defendants' labels—colchicine blood levels had increased 65% and were still accumulating notwithstanding the safety implications of the narrow therapeutic index of colchicine.

131. Based on these discoveries, the FDA has required Mutual's approved labels to include the foregoing important information regarding the circumstances and dosing regimens that result in dangerous increases in colchicine blood levels.

132. In fact, the FDA has required Mutual to also implement a Risk Evaluation and Mitigation Strategy ("REMS") program and an FDA-approved Medication Guide alerting patients to the potential for serious drug-drug interactions with colchicine and increased susceptibility to severe colchicine toxicity in patients with renal or hepatic impairment.

133. In approving COLCRYS™, the FDA noted several important safety issues that are addressed by the COLCRYS™ label, but that are not addressed in Defendants' unapproved product labels. Specifically, the FDA noted that the correct dosing of COLCRYS™ significantly reduced adverse events. The FDA also noted that the COLCRYS™ product insert/labels warn about potentially life-threatening drug-drug interactions that can occur unless the proper dosing is followed. These interactions can occur even at prescribed doses of colchicine, and

with medications that are given for a limited time, such as antibiotics. *See* FDA MedWatch: Colchicine Marketed as COLCRYS - (http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm174596.htm); FDA Drug Safety and Availability Information for Healthcare Professionals: New Safety Information for Colchicine (marketed as COLCRYS)(http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm174315.htm)

134. In its release dated July 30, 2009, the FDA highlighted important safety considerations found in the approved COLCRYS™ prescribing information, which is designed to assure safe use of COLCRYS™: "First, FDA analyzed safety data for colchicine from adverse events reported to the Agency, the published literature, and company-sponsored pharmacokinetic and drug interaction studies. This analysis revealed cases of fatal colchicine toxicity reported in certain patients taking standard therapeutic doses of colchicine and concomitant medications that interact with colchicine, such as clarithromycin. These reports suggest that drug interactions affecting the gastrointestinal absorption and/or hepatic metabolism of colchicine play a central role in the development of colchicine toxicity. Second, data submitted supporting the safety and efficacy of Colcrys in acute gout flares demonstrated that a substantially lower dose of colchicine was as effective as the higher dose traditionally used. Moreover, patients receiving the lower dose experienced significantly fewer adverse events compared to the higher dose."

135. None of this critical safety information appears on the labeling and packaging of Defendants' unapproved colchicine tablets. Defendants are not required to have a REMS program or Medication Guide for their colchicine products because they are not FDA-approved.

136. Thus, Defendants' deficient labels not only pose a serious risk to the public, but will make Plaintiffs' COLCRYS™ product appear to be *more* dangerous

than Defendants' unapproved and illegal colchicine products when in fact the opposite is true.

137. Defendants' practices irreparably damage Plaintiffs because they will confuse and mislead physicians, pharmacists, buyers, patients and others into falsely believing that Plaintiffs' COLCRYS™ product is dangerous, unsafe and fraught with risk compared to Defendants' misleadingly and deceptively labeled products.

138. Indeed, without judicial intervention, it would not be unreasonable for consumers to ask, for example, why the FDA requires Mutual to list the additional potentially negative drug-drug interactions, food interactions and contraindications as well as other warnings regarding its FDA-approved COLCRYS™ product that are not "required" or included with Defendants' illegal, non-FDA-approved products.

139. This confusion, which directly arises from Defendants' unfair competition and false advertising, causes irreparable harm to Plaintiffs.

FIRST CAUSE OF ACTION

(FALSE ADVERTISING OR MISLEADING REPRESENTATION OF FACT AND UNFAIR COMPETITION UNDER 15 U.S.C. § 1125(A) AGAINST DEFENDANTS)

140. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1-139 of this Complaint.

141. Defendants advertise, market, promote and distribute their non-FDA approved colchicine products throughout the United States and California to drug wholesalers, distributors, drug store chains, independent pharmacies and others.

142. On information and belief, Defendants engage in such acts in a manner that misleads relevant consumers into believing that their colchicine products are comparable to and/or safer than Mutual's FDA-approved COLCRYS™ product.

143. Defendants' colchicine product labels, instructions for use, commercial advertising and promotions, including the placing of the aforementioned misleading information in advertising channels including Price Lists, Wholesaler Ordering Systems, drug ordering systems used by drug store chains, and Internet websites,

constitute false and misleading descriptions or representations of fact that their colchicine products are safe, effective and/or FDA-approved, and that the safety and warning information provided with Defendants' unapproved colchicine products is complete.

144. On information and belief, members of the public (including pharmacists, purchasers, caregivers, patients and physicians) are misled by Defendants' misrepresentations and/or descriptions of fact, understanding them alone and/or together to claim that Defendants' colchicine products are safe, effective and/or FDA-approved. Defendants' commercial advertising and/or promotions thus misrepresent the nature, characteristics and qualities of their unapproved colchicine products.

145. As a direct result of Defendants' acts of false and misleading descriptions of fact, false and misleading representations and false and/or deceptive advertising and unfair competition, Plaintiffs have suffered, currently suffer, and will continue to suffer damage and irreparable injury, including injury to their business, reputation and goodwill..

146. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting for profits made by Defendants on sales of colchicine products, as well as recovery of costs of this action. Furthermore, Plaintiffs are informed and believe, and on that basis allege, that Defendants' conduct was undertaken willfully and with the intention of causing confusion, mistake or deception, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117.

147. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As such, Plaintiffs are entitled to injunctive relief as set forth in 15 U.S.C. § 1116.

SECOND CAUSE OF ACTION

(STATUTORY UNFAIR COMPETITION UNDER CALIFORNIA BUSINESS AND PROFESSIONS CODE § 17200 AGAINST DEFENDANTS)

148. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1-147 of this Complaint.

149. On information and belief, Defendants are illegally distributing and/or selling drug products containing colchicine as the sole active ingredient for which they have not obtained FDA approval pursuant to the Federal FDCA.

150. On information and belief, Defendants have made, published, disseminated and circulated false, deceptive and misleading statements, representations and advertisements in California, thereby misrepresenting the nature, quality and characteristics of their colchicine products with the intent of selling, distributing and increasing the consumption of, and interest in, their colchicine products.

151. On information and belief, Defendants have intentionally deceived the public by misrepresenting that their colchicine products have been approved for sale under the Federal FDCA.

152. By the actions alleged in this Complaint, Defendants have engaged in unlawful and unfair Competition under the statutory law of the State of California, Cal. Bus. & Prof. Code § 17200, *et seq.*

153. As a result of Defendants' actions described herein, Plaintiffs have suffered and will continue to suffer damage to their business, reputation and goodwill.

154. As a direct and proximate result of Defendants' willful and intentional actions, Plaintiffs have suffered damages in an amount to be determined at trial and, unless Defendants are restrained, Plaintiffs will continue to suffer irreparable damage.

THIRD CAUSE OF ACTION

(STATUTORY FALSE ADVERTISING UNDER CALIFORNIA BUSINESS AND PROFESSIONS CODE § 17500 AGAINST DEFENDANTS)

155. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1- 154 of this Complaint.

156. On information and belief, Defendants advertise, market, promote, sell and distribute their colchicine products to drug wholesalers and distributors, drug store chains, pharmacies and others.

157. On information and belief, Defendants intend purchasers and users to believe that their colchicine products are comparable to or interchangeable with Plaintiffs' FDA-approved COLCRYS™ product and, when Plaintiffs launch COLCRYS™ in the marketplace, to substitute Defendants' unapproved colchicine products for prescriptions of Plaintiffs' FDA-approved COLCRYS™ product on that basis.

158. Defendants' colchicine product labels, product inserts, commercial advertising and/or promotion, including the listing and advertising of unapproved colchicine drugs via advertising channels including Price Lists, Wholesaler Ordering Systems, drug ordering systems used by drug store chains, and Internet websites, constitute false or misleading descriptions or representations that their colchicine products are safe, effective and approved by the FDA.

159. Defendants' recommendations of dosage and administration of their colchicine products in their labels, product inserts, commercial advertising or promotions, constitute false or misleading descriptions or representations of fact.

160. Consumers are misled by Defendants' representations, understanding them alone and/or together to claim that Defendants' colchicine products are safe, effective and FDA approved for the treatment and prevention of FMF and/or gout flares.

161. By any and/or all of the actions set forth in this Complaint, Defendants

have engaged in false advertising under the statutory law of the State of California, Cal. Bus. & Prof. Code § 17500, *et seq.*, by making such untrue or misleading statements in advertisements and/or promotions.

162. Defendants knew or should have known that their statements were false or likely to mislead purchasers.

163. As an actual and proximate result of Defendants' willful and intentional actions set forth herein, Plaintiffs have suffered damages in an amount to be determined at trial, and unless Defendants are restrained, Plaintiffs will continue to suffer irreparable harm.

FOURTH CAUSE OF ACTION

(COMMON LAW UNFAIR COMPETITION BASED UPON DEFENDANTS' MISAPPROPRIATION OF PLAINTIFFS' PROPERTY)

164. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1- 163 of this Complaint.

165. On information and belief, Defendants have implicitly and explicitly made false and misleading misrepresentations in California to drug wholesalers, distributors, drug stores, pharmacies, pharmacists, patients and others, that their colchicine products are FDA approved and/or comparable or equivalent to Plaintiffs' FDA-approved COLCRYS™ product, and that their unapproved colchicine products can be substituted for prescriptions for Plaintiffs' FDA-approved COLCRYS™ product.

166. On information and belief, Defendants have deceptively and intentionally failed to inform purchasers and users that their colchicine products have not been approved by the FDA, and have not been tested or demonstrated to be therapeutically equivalent to Plaintiffs' FDA-approved COLCRYS product.

167. On information and belief, Defendants' selective and misleading representations and omission of relevant facts as to (i) the lack of FDA approval of their colchicine products and (ii) purported equivalency to Plaintiffs' FDA-

approved COLCRYS product, are likely to cause confusion, mistake or deception concerning the nature, characteristics and qualities of their unapproved colchicine products in comparison, connection, or association with Plaintiffs' FDA-approved COLCRYS product.

168. On information and belief, Defendants know or reasonably should know that their adverting and marketing programs encourage the sale of their unapproved colchicine products, and when Plaintiffs launch COLCRYS in the marketplace, are likely to result in unlawful substitution of their unapproved colchicine products for Plaintiffs' COLCRYS product, and are likely to deceive doctors, pharmacists, patients and others, about the nature, characteristics and qualities of their colchicine products in comparison, connection, or association with COLCRYS.

169. Mutual has invested significant amounts of time, skill, money and resources in testing and qualifying its colchicine for the treatment of FMF and gout flares, including working with the FDA in order to obtain FDA approval for COLCRYS™. Additionally, Mutual has made future time and cost consuming commitments to the FDA with respect to monitoring and reporting consumer side effects of its FDA-approved COLCRYS™ product.

170. By their actions, Defendants' have misappropriated Plaintiffs' property in the form of their time, effort, goodwill, reputation and the unique FDA approval status of their FDA-approved COLCRYS™ product.

171. Defendants' appropriation was without Plaintiffs' authorization or consent, and was accomplished through little or no cost to Defendants.

172. By their actions, Defendants have engaged in misappropriation of Plaintiffs' property under the common law of the State of California and, as a result, Plaintiffs have suffered and will continue to suffer damage to their business, reputation and goodwill.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment against Defendants as follows:

A. That Defendants and all of their respective officers, agents, servants, representatives, employees, attorneys, and all other persons acting in concert with them be preliminarily and permanently enjoined from:

1. listing of their unapproved colchicine products on Price List prescription drug dispensing databases, including but not limited to Medi-Span, First Databank, Gold Standard and Redbook;

2. listing of their unapproved colchicine products on Wholesaler Ordering Systems, including but not limited to those provided by McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda, Inc., and Kinray, Inc.;

3. listing of their unapproved colchicine products on pharmacy and drug store computer systems and/or government drug product databases, including the Federal Supply Schedule;

4. directly or indirectly engaging in false advertising or promotions of their colchicine products or inducing others to substitute Defendants' colchicine products for prescriptions of Mutual's FDA-approved COLCRYS™ product;

5. making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution (including but not limited to repackaging) of Defendants' colchicine products in such a fashion as to suggest that such product is a generic or therapeutic equivalent to Plaintiffs' FDA-approved COLCRYS™ product, or can be interchanged with or substituted for prescriptions of Plaintiffs' FDA-approved COLCRYS™ product;

6. directly or indirectly engaging in false advertising or promotions

of their colchicine products as FDA approved;

7. marketing, selling, and distributing colchicine drug products for the treatment of FMF and/or gout flares;

B. That Defendants be ordered to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of either Defendants' colchicine drug products or Mutual's FDA-approved COLCRYS™ product, including without limitation:

1. the sending of a registered letter to (with a copy to Plaintiffs) to all Price Lists databases which list Defendants' colchicine products, including but not limited to Medi-Span, First Databank, Gold Standard and Redbook, requesting that their unapproved colchicine products be immediately listed as obsolete in said Price List databases, and instructing them to remove any listing of colchicine products with colchicine as the sole active ingredient in said Price List databases as soon as commercially possible;

2. the sending of a registered letter to (with a copy to Plaintiffs) to all wholesalers which list Defendants' colchicine products on their respective Wholesaler Ordering Systems, including but not limited to McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation, Anda, Inc., and Kinray, Inc., requesting that their unapproved colchicine products be immediately listed as obsolete in said Wholesaler Ordering Systems, and instructing them to remove any listing of colchicine products having colchicine as the sole active ingredient in said Wholesaler Ordering Systems as soon as commercially possible;

3. the sending of a registered letter to (with a copy to Plaintiffs) to all pharmacies which Defendants know or have reason to believe have received the false and misleading advertising, instructing them to remove all listings of unapproved colchicine products from their pharmacy computer systems;

4. the sending of a registered letter (with a copy to Plaintiffs) to all government drug product databases on which their unapproved colchicine products

are listed, including but not limited to the Federal Supply Schedule, instructing them to remove all listings of their unapproved colchicine products;

5. the placement of corrective advertising to prevent the inducement of others from substituting Defendants' products for prescriptions of Mutual's FDA-approved COLCRYS™ product; and

6. providing notice to the purchasing, dispensing, ordering and prescribing public (including pharmacists, doctors and purchasers or buyers of such products) that the FDA has approved only Plaintiffs' COLCRYS™ product for FMF and gout flares and no other indication has been proven effective;

C. That Defendants be adjudged to have violated the provisions of 15 U.S.C. § 1125(a) and (b) by unfairly competing against Plaintiffs by using false or misleading descriptions or representations of fact that misrepresent the nature, quality and characteristics of their unapproved colchicine products and unlawfully importing mislabeled products into the United States;

D. That Defendants be adjudged to unlawfully and unfairly compete against Plaintiffs under the laws of the State of California, Cal. Bus. & Prof. Code § 17200, *et seq.*;

E. That Defendants be adjudged to have competed unfairly against Plaintiffs by engaging in false or misleading advertising under the laws of the State of California, Cal. Bus. & Prof. Code § 17500, *et seq.*;

F. That Defendants be adjudged to compete unlawfully and unfairly against Plaintiffs under the common law of the State of California by misrepresenting to the public that their colchicine products have been approved for sale by the FDA;

G. That Defendants be adjudicated to have unlawfully misappropriated Plaintiffs' time, money and resources in obtaining FDA approval for their colchicine drug;

H. That Defendants recall and remove all their illegal, unapproved product from the distribution supply chains;

I. That Plaintiffs be awarded damages pursuant to 15 U.S.C. § 1117(a), sufficient to compensate it for the damage caused by Defendants' false and misleading statements;

J. That Plaintiffs be awarded Defendants' profits derived by reason of said acts, or as determined by said accounting;

K. That such damages and profits be trebled and awarded to Plaintiffs and that it be awarded its costs, attorneys' fees and expenses in this suit under 15 U.S.C. § 1117, as a result of Defendants' willful, intentional and deliberate acts in violation of the Lanham Act;

L. That Plaintiffs be awarded damages in an amount sufficient to compensate it for the damage caused by Defendants' unfair competition and false advertising under California Business and Professions Code §§ 17200 and 17500 and common law, including exemplary damages provided by § 17206 of the California Business and Professions Code;

M. That Plaintiffs be granted injunctive relief under California Business and Professions Code §§ 17200, § 17500 and 15 U.S.C. § 1116 *et seq.*;

N. That all of Defendants' misleading materials and products be destroyed as allowed under 15 U.S.C. § 1118;

O. That Defendants file, within ten days from entry of an injunction, a declaration with this Court signed under penalty of perjury certifying the manner in which Defendants have complied with the terms of the injunction;

P. That Plaintiffs be granted prejudgment and post-judgment interest;

Q. That Plaintiffs be granted costs associated with the prosecution of this action; and

R. That Plaintiffs be granted such further relief as the Court may deem just.

Dated: August 4, 2009

COOLEY GODWARD KRONISH LLP

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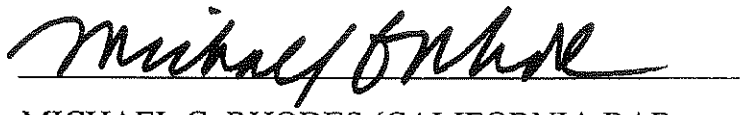
MUTUAL PHARMACEUTICAL COMPANY, INC., AR SCIENTIFIC, INC., and AR HOLDING COMPANY, INC.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and Local Rule 38-1, Plaintiffs demand a trial by jury on all issues triable of right by a jury.

Dated: August 4, 2009

COOLEY GODWARD KRONISH LLP



MICHAEL G. RHODES (CALIFORNIA BAR NO. 116127)
PETER J. WILLSEY (*Pro Hac Vice* pending)
JOHN S. KYLE (CALIFORNIA BAR NO. 199196)
NISHAN KOTTAHACHCHI (CALIFORNIA BAR NO. 221612)
BRENDAN J. HUGHES (*Pro Hac Vice* pending)

Attorneys for Plaintiffs
MUTUAL PHARMACEUTICAL COMPANY, INC., AR SCIENTIFIC, INC., and AR HOLDING COMPANY, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Percy Anderson and the assigned discovery Magistrate Judge is Rosalyn M. Chapman.

The case number on all documents filed with the Court should read as follows:

CV09- 5700 PA (RCx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[X] Western Division
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[ ] Southern Division
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] Eastern Division
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

AO 440 (Rev. 02/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of California

MUTUAL PHARMACEUTICAL COMPANY, INC., a Pennsylvania corporation; AR SCIENTIFIC, INC., a Delaware corporation; and AR HOLDING COMPANY, INC., a Delaware corporation

Plaintiff's

v.

WATSON PHARMACEUTICALS, INC., a Nevada corporation; WEST-WARD PHARMACEUTICAL CORP., a Delaware corporation; GENERICS BIDCO I, LLC dba QUALITEST PHARMACEUTICALS, a Delaware corporation; VISION PHARMA, LLC, a New Jersey corporation; and EXCELLIUM PHARMACEUTICAL, INC., a New Jersey corporation

Defendants

Civil Action No. CV09-05700 PA (RCx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 20 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Michael G. Rhodes
Cooley Godward Kronish LLP
4401 Eastgate Mall
San Diego, CA 92121-1909
(858) 550-6000

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 5 AUG 2009

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____ _____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)	DEFENDANTS
Mutual Pharmaceutical Co., Inc., AR Scientific, Inc., and AR Holding Company, Inc.	Watson Pharmaceuticals, Inc., West-ward Pharmaceutical Corp., Generics Bidco I, LLC dba Qualitest Pharmaceuticals, Vision Pharma, LLC, and Excellium Pharmaceutical, Inc.
(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Michael G. Rhodes, Cooley Godward Kronish LLP 4401 Eastgate Mall San Diego, California 92121 (Tele: 858-550-6000)	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff ☑ 3 Federal Question (U.S. Government Not a Party)

☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: **JURY DEMAND:** ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☑ **MONEY DEMANDED IN COMPLAINT:** $ To be determined at trial

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

False and Misleading Advertising, False Misrepresentation of Fact, and Unfair Competition under 15 U.S.C. Sec. 1125(A)

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☑ 890 Other Statutory Actions
- ☐ 891 Agricultural Act
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Info. Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpractice
- ☐ 365 Personal Injury-Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus-Alien Detainee
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 444 Welfare
- ☐ 445 American with Disabilities - Employment
- ☐ 446 American with Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus/ Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/ PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety /Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: CV09-05700

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	Mutual Pharmaceutical Company, Inc. - Philadelphia County, Philadelphia, Pennsylvania

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	AR Scientific, Inc. - Philadelphia County, Philadelphia, Pennsylvania

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	AR Holding Company, Inc. - New Castle County, Wilmington, Delaware

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): Michael Gottsch **Date** August 4, 2009

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))